

Appl. No. 10/750,755  
Amendment dated: April 20, 2006  
Reply to OA of: January 20, 2006

### **REMARKS**

This is in response to the outstanding Official Action of January 20, 2006. As indicated in the Interview Summary, the prior art rejection was withdrawn for the reasons submitted in the amendment filed February 15, 2005, which were reiterated at the interview. Thus, the reasons set forth in the previous response make of record the substance of the interview and are herein incorporated by reference. The only issues remaining are with respect to those of outstanding Official Action.

The rejection of claims 4, 5, 12, 13, 18, 19 and 20 under 35 USC 112 has been obviated by the cancellation of these claims from the application without prejudice or disclaimer. Claims 6 and 20 have been further amended to obviate the specific aspects of the rejection set forth in the Official Action and as fully supported by the specification as originally filed. New claims 23 and 24 have been added to the application to further aspects of the invention and in view of the amendments to the claims. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 9-14 under 35 U.S.C. 102(b) as being anticipated by JP'744 has been carefully considered but is most respectfully traversed in view of the amendment to the claims and the following comments. In the rejection, it is urged that the prior art teaches a method of improving the castability of a titanium alloy but does not identify where in the reference this property is taught by the reference. In fact, only an English abstract is provided. No translation is provided even though the Japanese patent is listed as a reference.

In this regard, the Examiner's attention is most respectfully directed to MPEP § 706.02 as the present rejection appears to rely upon a reference in the Japanese

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language. As noted in this section of the manual, prior art uncovered in searching the claimed subject matter of a patent application often includes English language abstracts of underlying documents, such as technical literature or foreign patent documents which may not be in the English language. When an abstract is used to support a rejection, the evidence relied upon is the facts contained in the abstract, not additional facts that may be contained in the underlying full text document. Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art. See *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (unpublished).

To determine whether both the abstract and the underlying document are prior art, a copy of the underlying document must be obtained and analyzed. If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection. The record must also be clear as to whether the examiner is relying upon the abstract or the full text document to support a rejection. The rationale for this is several-fold. It is not uncommon for a full text document to reveal that the document fully anticipates an invention that the abstract renders obvious at best. The converse may also be true, that the full text document will include teachings away from the invention that will preclude an obviousness rejection under 35 U.S.C. 103, when the abstract alone appears to support the rejection. An abstract can have a different effective publication date than the full text document. Because all patentability determinations are fact dependent, obtaining and considering full text documents at the earliest practicable time in the examination process will yield the fullest available set of facts upon which to determine patentability, thereby improving quality and reducing pendency.

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When both the abstract and the underlying document qualify as prior art, the underlying document should normally be used to support a rejection. If this rejection is maintained, an English language translation of the reference is most respectfully requested in the next Official Action.

The abstract relied upon in the rejection states that the purpose is to obtain Ti alloy with improved crevice corrosion and the essential element, in addition to Ti, is a Pt group element. On the contrary, the presently claimed invention is directed to a technique to improve the castability of titanium alloy and the essential element is Bi. Further, newly amended claims do not contain a Pt element. How can one of ordinary skill in the art conceive the presently claimed invention from the teaching of the primary reference. Is there a teaching as to the relationship between the "crevice corrosion" and "castability" of the titanium alloy. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of Claims 1-8 and 15-22 under 35 U.S.C. 103(a) as being unpatentable over JP'744 in view of Prasad (US Pat. No. 5,091,148) has been carefully considered but is most respectfully traversed. It is urged in the Official Action that JP'744 discloses the invention substantially as claimed (see paragraph 5 above). As noted above, this statement is specifically traversed. Moreover, the necessary motivation to combine the teachings and arrive at the presently claimed invention is not present in the prior art.

It is recognized in the rejection that JP'744 does not disclose wherein the alloy is in the form of a medical device. Prasad discloses an **analogous** (emphasis added) titanium alloy for forming a medical device (e.g., a dental casting, see abstract). Where is there any teaching that the compositions are analogous and one of ordinary skill in the art would be motivated to combine the teachings? Obvious to try is not the standard of obviousness under 35 USC 103.

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The present invention relates to a medical device made of a biocompatible titanium alloy having improved castability and a method to improve the castability of a titanium alloy. Thus, as a threshold matter, JP'744 does not disclose the invention substantially as claimed because this reference is directed to titanium alloy which has superior crevice corrosion resistance and no utility for the composition is described. Castability is the ability of casting, where casting is defined as 1) an object at or near finished shape obtained by solidification of a substance in a mold or 2) pouring molten metal into a mold to produce an object of desired shape.

The present invention focuses on improving castability by way of introducing Bi into the Ti alloy. Improved castability is also beneficial since a cost-effective way to manufacture Ti alloys is by near-shape casting which requires little or no machining. Ti alloys are inherently difficult to cast due to their high melting temperatures and high chemical reactivity. The present invention provides a simple and effective method to improve castability.

Because titanium is inherently difficult to cast due to its high melting point and high reactivity, the present invention is directed to a medical device having improved castability consisting essentially of a titanium alloy and a method to improve a titanium alloy wherein the castability is greatly improved. Applicants have discovered that the introduction of Bismuth in certain amounts to various titanium alloys achieves the goal of improved castability. Such improvement can clearly be seen by referring to the comparative examples summarized in Table 1 of the application. When bismuth was melted into the various titanium samples, the castability was improved over the same titanium sample without the bismuth. Applicants further discovered that the addition of more bismuth to the titanium alloys caused the improved castability to decrease, although the castability was still improved with reference to the titanium alloy containing no bismuth.

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Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The present invention claims a medical device made of a biocompatible titanium alloy composition having an improved castability consisting essentially of about 0.01-5 wt% Bi based on the weight of the alloy composition; at least one alloy element selected from a group consisting of Mo, Nb, Ta, Zr and Hf; and the balance Ti.

The transitional phrase "consisting of" excludes any element, step or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). Thus, the Kimura reference, which uses the transitional phrase "consisting of" in both the claims and the specification, is limited to teaching only that which is specifically identified in the embodiments set forth in the disclosure and claims. Accordingly, in order to support a §103(a) rejection, JP'744 must be modified by a motivational statement or suggestion that explains why it would be obvious to one having ordinary skill in the art to add and/or remove elements specifically required by the closed language of the claims and specification. The Office Action has not provided a motivation or suggestion as to why it would have been obvious to one of ordinary skill in the art to use the alloy with a noble metal.

Further, as mentioned above, a §103(a) rejection is only proper when the reference teaches or suggests all of the claim limitations. The Prasad reference requires a noble metal in the medical device not required by the presently claimed invention.

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Section 2143.03 of the MPEP states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

With respect to claim 15, it is urged that JP'744 that further discloses a method of making an article using a titanium alloy consisting essentially of 0.01-5wt% Bi (e.g., 0.05-2.00 % Bi, see the constitution portion of the abstract), at least one alloy selected from the group consisting of Mo, Nb, Ta, Zr, and Hf (e.g., Nb, Ta, Zr, and Hf, see the abstract), and the balance Ti. JP'744 fails to specify a method of making a medical device including casting the titanium alloy. Prasad discloses a method of making a medical device (e.g., a dental casting, see the abstract) by casting using an analogous titanium alloy. It would have been obvious to modify the method of JP'744 so as to have formed a medical device by casting as suggested by Prasad since Prasad discloses that an analogous titanium alloy can be used in a method for forming a medical device using an analogous titanium alloy. This aspect of the rejection is specifically traversed in view of the above comments.

With respect to claim 17, it is urged in the Official Action that JP'744 discloses a method of making an article using a titanium alloy consisting essentially of 0.01-5wt% Bi (e.g., 0.05-2.00 % Bi, see the constitution portion of the abstract), at least one eutectoid beta stabilizing agent selected from the group consisting of Mo, Nb, Ta, Zr, and Hf (e.g., Nb Ta, Zr, and Hf, see the abstract), at least one eutectoid beta stabilizing agent selected from the group consisting of Fe, Cr, Mn, Co, Ni, Cu, Ag, Pd, Si, and Sn (e.g., the Pt group elements including Ag, Au, and Pd, see the constitution portion of the abstract), and the balance Ti. JP'744 fails to specify a method of making a medical device including casting the titanium alloy. Prasad discloses a method of making a medical device (e.g., a dental casting, see the abstract) by casting using an analogous titanium alloy. It would have been obvious to modify the method of JP'744 so as to


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have formed a medical device by casting as suggested by Prasad since Prasad discloses that an analogous titanium alloy can be used in a method for forming a medical device using an analogous titanium alloy. This aspect of the rejection is specifically traversed in view of the above comments.

In view of the above comments and amendments to the claims an early and favorable action on the application is now in order and is most respectfully requested.

Respectfully submitted,

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